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(54) Packaged catheter with lubricant-activating liquid

(57) A sealed sterile flexible package contains a medical device, for example a urethral catheter (1), for insertion into a body orifice of a patient for use in the treatment or examination thereof, the device having a coating of a material which, when brought into contact with an activating liquid, becomes lubricating. The package also contains containment means (9) therein for holding a quantity of the activating liquid such as water, the containment means being manipulable from outside the package so as to release the liquid therefrom into contact with the device before the package is opened. The containment means (9) may be a vial of non-brittle plastics which can be sheared at a neck portion (10), or a rupturable sealed compartment or pouch (20, Figure 2). The outer package (6) may be of plastics film with heat-sealed ends (7,8).

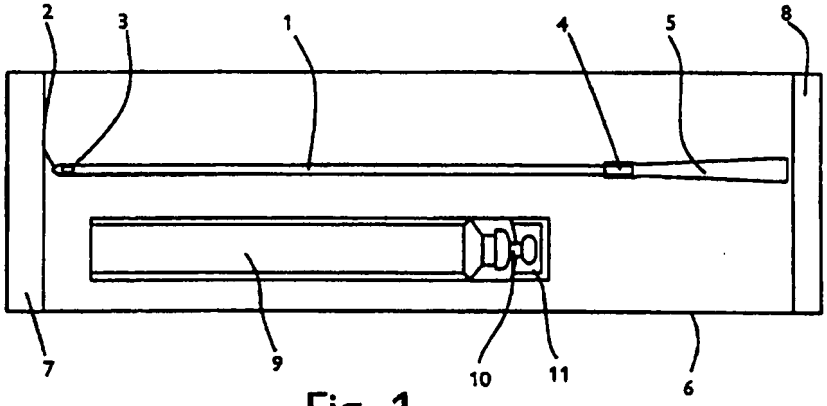

Fig 1

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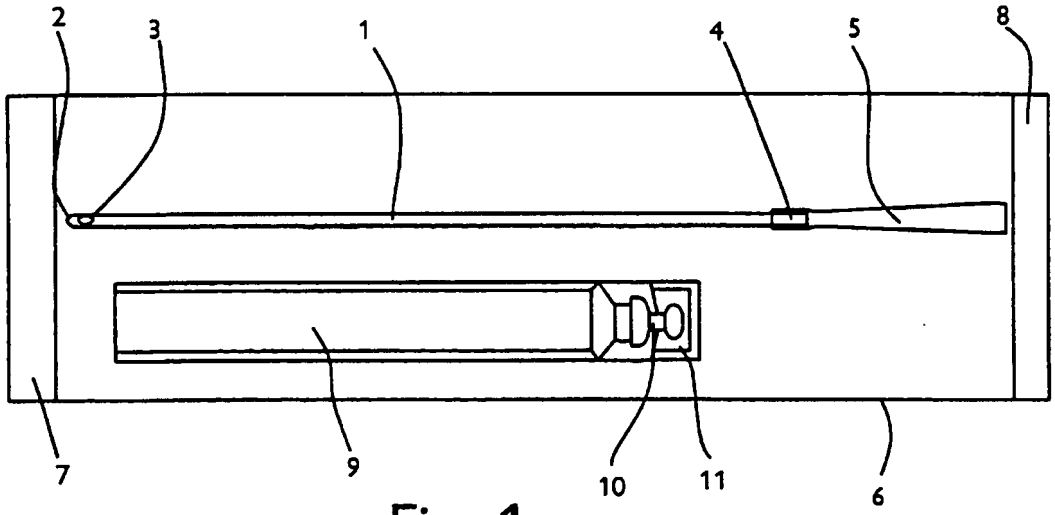

Fig 1

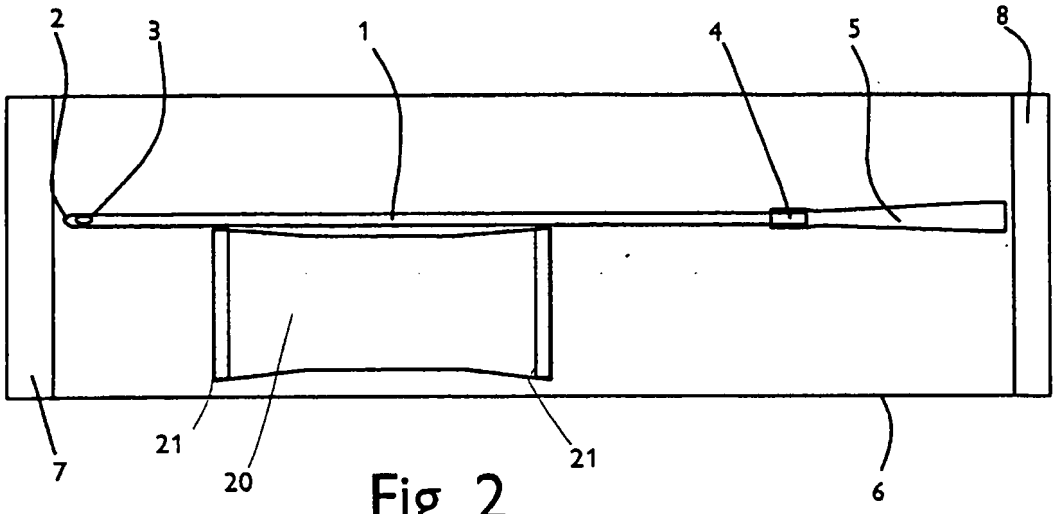

Fig 2

PACKAGED MEDICAL DEVICE

Field of the Invention

This invention relates to a medical device, and especially to a packaged catheter for self administration by the patient.

Background to the Invention

One type of catheter for intermittent self-catheterisation is known as a Nelaton catheter, and comprises a flexible plastics tube having a rounded tip and, typically, two side eyes. Such catheters are used to drain urine from the bladder, the patients themselves inserting the catheter into the bladder via the urethra. The catheter is usually removed as soon as the bladder has been voided, although it can sometimes be left in longer, and then disposed of. In recent years, so-called lubricious coatings have been developed for catheters which, when wetted, make the surface of the catheter extremely slippery and therefore easier and less painful to insert. The catheters may be supplied in waterproof packs, so as to provide a receptacle to fill with water to activate the coating ready to insert into the bladder.

A major problem with self-catheterisation in particular is the risk of infection. With coated catheters to be inserted at home, the usual instruction is to use tap water to activate the coating. Alternatively, sterile water can be used, if available. Tap water can contain large numbers of organisms, and therefore involve a risk of infection, and even if sterile water is used, there is a risk of contamination of the catheter once the package has been opened to immerse the catheter in water. If the procedure is carried out in a public convenience, the risk of infection increases dramatically, even where sterile water is used.

Summary of the Invention

According to the invention, there is provided a sealed sterile flexible package containing a medical device for insertion into a body orifice of a patient for use in the treatment or examination thereof, the device having a coating of a material which, when brought into contact with an activating liquid, becomes lubricating, the package also containing containment means therein for holding a quantity of the activating liquid, the containment means being manipulable from outside the package so as to release the liquid therefrom into contact with the device before the package is opened.

The medical device may, for example, be a catheter. The coating may be a hydrophilic lubricious coating, the containment means holding a quantity of sterile water.

The containment means may comprise an openable vial alongside the medical device within the package. Preferably, the vial is formed of a material which can be broken to release the liquid therefrom without the formation of any sharp fragments which might adhere to the medical device and cause injury to the patient. For example, non-brittle plastics materials may be used.

Alternatively, the containment means comprises a sealed compartment within the package with a selectively rupturable wall separating the liquid from the coated medical device, e.g. the catheter. Typically, the package will be formed of a plastics film material, and the sealed compartment may therefore be formed by selectively heat-sealing the plastics film in the same manner as is employed for the manufacture of the package itself.

In another alternative embodiment, the containment means comprises a sealed pouch formed of a plastics film material or the like and arranged such that pressure on the pouch through the bag causes the material to rupture, or a seam or other joint to fail, thus releasing the liquid.

Since packaged medical devices such as catheters are typically sterilised by exposure to gamma radiation, the risk of contamination of the liquid during the packaging process is avoided, the containment means and its charge of liquid being sterilised in the same process after packaging.

While there will always be a risk of some contamination of the catheter or other medical device as soon as the sterile package in which it is supplied is opened, if the catheter is inserted immediately upon opening of the package, that risk will be very small. It will be seen, therefore, that since the wetting of catheter is carried out, in accordance with the present invention, before the sterile package is opened, the wetting process itself no longer contributes to the risk of contamination, and therefore use of the packaged catheter of the invention involves substantially lower risk of infection being introduced than with conventionally-packaged catheters.

The medical device of the invention may be any device suitable for use by the patient for self treatment, or by a medical practitioner or other medically-trained person, or even for veterinary use, where lubrication and sterility are important features.

Brief Description of the Drawing

In the drawing, which illustrate exemplary embodiments of the invention:

Figure 1 shows, in plan, a packaged catheter in accordance with one embodiment; and

Figure 2 shows a corresponding view of an alternative embodiment.

Detailed Description of the Illustrated Embodiment

Referring to Figure 1, the catheter 1 is of conventional construction, consisting of an elongate flexible tube having one end 2 closed, and two side eyes or inlets 3 (of which only one is visible in the drawing) one adjacent to the end and one spaced from it by a small distance. The other end 4 of the tube is provided with an attached tapered member 5 serving as an outlet for the released urine from within the bladder. The tapered connector 5 may also be connected to a suitable receptacle, for example a drainage bag. The flexible tube part of the catheter is coated with a hydrophilic material which, when it has absorbed water, becomes highly lubricating. For example, a typical coating comprises a mixture of ethyl lactate and poly(vinyl pyrrolidone). Such coatings may simply be applied in solution form and allowed to dry, or they may be cured by the use of ultra violet radiation.

The catheter 1 is packaged within a plastics bag 6 which is heat-sealed at the ends 7 and 8 thereof. The plastics material from which the bag is formed is such as to be treatable with gamma radiation without deterioration. Also contained within the bag 6 is a plastics vial 9 containing a sample of sterile water sufficient to activate the coating on the catheter when released. The vial 9 is formed with a narrow neck portion 10 which terminates in a tab portion 11 not securely attached to the body of the vial, so that twisting of the tab portion 11 relative to the body shears the neck portion 10, releasing the contents of the vial (water) into contact with the catheter, activating the coating. The vial 9 is formed so as to be compressible to expel water therefrom. Since the bag 6 is formed of a relatively thin flexible plastics material, the twisting of the tab portion 11 and the compression of the vial can be readily effected while the bag 6 remains sealed, thus avoiding any risk of microbial contamination of the catheter. It will be seen that any gamma radiation treatment of the package to sterilise it will also sterilise the vial and its

contents, although the vial can be produced in such a manner as to ensure the sterility of its contents before it is sealed in to the bag 6.

The vial is formed of a non-brittle plastics material for example polypropylene so that the neck portion 10 can readily be sheared without risk of release of any sharp fragments to jeopardise safe use of the catheter.

Referring now to Figure 2, in which like components have the same reference numerals as in Figure 1, the vial is replaced with a pouch 20 formed of a plastics film. Conveniently, the film is produced in the form of a continuous tube which is then formed into pouches by welding the material transversely to form a seam 21, and introducing the liquid before making the next seam 21 at a predetermined distance from the last seam. The seams are formed sufficiently wide to permit the pouches to be separated from each other by cutting transversely. The pouches can be formed of relatively thin materials, so as to be readily ruptured by the application of manual pressure thereon. Alternatively, the welds are made in such a manner as to permit the film surfaces to separate as a result of the internal pressure induced when the pouch is squeezed through the bag 6.

CLAIMS

1. A sealed sterile flexible package containing a medical device for insertion into a body orifice of a patient for use in the treatment or examination thereof, the device having a coating of a material which, when brought into contact with an activating liquid, becomes lubricating, the package also containing containment means therein for holding a quantity of the activating liquid, the containment means being manipulable from outside the package so as to release the liquid therefrom into contact with the device before the package is opened.

2. A package according to Claim 1, wherein the medical device is a catheter.

3. A package according to Claim 1 or 2, wherein the coating is a hydrophilic lubricious coating, and the containment means holds a quantity of sterile water.

4. A package according to Claim 1, 2 or 3, wherein the containment means comprises an openable vial alongside the medical device within the package.

5. A package according to Claim 4, wherein the vial is formed of a material which can be broken to release the liquid therefrom without the formation of any sharp fragments.

6. A package according to Claim 5, wherein the vial is formed of a non-brittle plastics material.

7. A package according to Claim 1, 2 or 3, wherein the containment means comprises a sealed compartment within the package with a selectively rupturable wall separating the liquid from the coated medical device.

8. A package according to Claim 7, wherein the package is formed of a plastics film material, and the sealed compartment is formed by selectively heat-sealing the plastics film.

9. A sealed sterile flexible package, substantially as described with reference to, or as shown in, the drawing.

The Patent Office

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Claims searched:	1-9	**Date of search:**	3 November 1997

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.O): A5R(RCEX, RGED); B8C(CPA, CWA2)

Int Cl (Ed.6): A61M 25/00; B65D 81/32

Other: ONLINE:WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
Y	EP 0677299 A1	(VIA LOG) lines 17-41 of column 9	1-3, 7, 8
Y	WO 96/30277 A1	(COLOPLAST) lines 3-7 of page 1; line 5 of page 2 to line 9 of page 3	1-3, 7, 8
Y	US 4269310	(USON) lines 31-48 of column 1	1-3, 7, 8

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.